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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,008

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EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/791,008	Applicant(s) CHAN ET AL.	
	Examiner THEODORE J. STIGELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-21,24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-21 and 26 is/are allowed.
- 6) ☒ Claim(s) 1,2,5-16 and 24 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Objections

Claim 5 is objected to because of the following informalities: Claim 5 further recites that the polymer tube is a reinforced braid polymer tube. However, claim 1 of which claim 5 depends, already recites that the inflation component comprises a hypotube. The examiner can only find disclosure in the specification of using either the hypotube or the braided material separately, but not together. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 5-14, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al. (US 2004/0254528). The examiner references Figures 5a-5b for illustrative purposes but maintains that multiple embodiments read on the claims. Adams discloses a balloon catheter (80) comprising an elongate shaft (82) extending from the distal region to the proximal region and defining a working lumen therebetween, the elongate shaft having a proximal end, a distal end, an inner surface

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and an outer surface, a hub assembly (94) coupled to the proximal end of the elongate shaft, wherein the working lumen is in fluid communication with a lumen of the hub assembly, an inflatable compliant balloon (98) disposed about a portion of the distal region of the outer surface of the elongate shaft such that the shaft extends through the balloon, and an external inflation component (90) having an inner surface and an outer surface, and an inflation lumen in fluid communication with the balloon, wherein the external inflation component is disposed longitudinally along the outer surface of the elongate shaft such that the outer surface of the inflation component is disposed adjacent the outer surface of the elongate shaft, wherein the external inflation component includes a proximal segment and a distal segment extending distal of the proximal segment, wherein the proximal segment includes a metallic hypotube and the distal segment includes a polymer tube extending distal of the metallic hypotube (Adams discloses using hypotubes in portion 90, see at least paragraph [0053]), wherein the inflation component has a distal end inside the balloon (see Figure 5A), wherein the tube can be partially reinforced tube (see at least par.[0053]), wherein Adams further contemplates using nitinol as a material choice, and wherein the inflation component can be attached to outer tube by multiple ways including shrink tubing, adhesive, or bonding (product-by-process).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 6, 8-12, 15-16, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daneshvar (5,728,066) in view of Adams et al. (US 2004/0254528).

Daneshvar discloses most of the limitations recited in the independent claim (see final rejection for complete explanation) but fails to teach including a hypotube in the external inflation component. Adams discloses a similar catheter configuration to Daneshvar and teaches to include hypotubes in the inflation component for improved stiffness and kink resistance. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the device of Daneshvar with the hypotube of Adams. Daneshvar and Adams are analogous in the art of balloon catheters, especially balloon catheters with external inflation components. Additionally, one skilled in the art would recognize that having an external inflation component exposes the inflation lumen to outside forces that could crush the inflation lumen and thereby limit the inflation capabilities of the catheter. One skilled in the art would recognize that including a hypotube in the inflation component would drastically reduce this problem.

Claims 1-2, 6, 8-12, 15-16, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro et al. (5,027,812) in view of Adams et al. (US 2004/0254528). Shapiro discloses most of the limitations recited in the independent claim (see final rejection for complete explanation) but fails to teach including a hypotube in the external inflation component. Adams discloses a similar catheter configuration to Shapiro and teaches to include hypotubes in the inflation component for improved stiffness and kink resistance. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the device of Shapiro with the hypotube of Adams. Shapiro and Adams are analogous in the art of balloon catheters, especially balloon catheters with external inflation components. Additionally, one skilled in the art would recognize that having an external inflation component exposes the inflation lumen to outside forces that could crush the inflation lumen and thereby limit the inflation capabilities of the catheter. One skilled in the art would recognize that including a hypotube in the inflation component would drastically reduce this problem.

Allowable Subject Matter

Claims 17-21 and 26 are allowed.

Response to Arguments

Applicant's arguments with respect to claims 1-2, 5-16, and 24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,983,417 to Gribbons et al.
US 2004/0143240 to Armstrong et al.

Both references show hypotubes for supporting inflation lumen.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763